

Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 16 claims. All of these, except for claims 13-16 were cancelled in a Preliminary Amendment filed by Applicants. Claim 13 was amended in a Second Preliminary Amendment filed by Applicants on October 31, 2002 and which was apparently not received by the Examiner. In addition, new claims 17-22 have been added herein. Thus, the claims pending after entry of the present amendments will be 13-22.

II. The Amendments

Claims 15 and 16 have been amended to correct an obvious error in dependency. Support for new claim 17 may be found in page 9 of the specification, lines 18-20.

Support for claim 18 may be found on page 9 of the application, lines 26-28. Support for new claim 20 may be found on page 9, lines 23-25, and support for the remaining claims, *i.e.*, 19, 21 and 22, may be found on page 9, lines 23-28.

None of the amendments described above add new matter to the application, and their entry is therefore respectfully requested.

II. Resubmission of Second Preliminary Amendment

On page 3 of the Office Action, the Examiner indicates that there was a telephone conversation in which it was agreed that Applicant's undersigned attorney would file a Preliminary Amendment correcting certain informalities in the claims. The Examiner indicates that this document was never received.

In response, Applicant respectfully submits that they did, in fact, file a Second Preliminary Amendment on October 31, 2002. This was filed by facsimile and a copy of the return cover page and the Second Preliminary Amendment itself is enclosed herewith. It is respectfully requested that this document be entered and that the modifications to claim 13 presented therein be incorporated into the present application.

The Rejections

On pages 2 and 3 of the Office Action, all pending claims are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Examiner mentions problems with respect to claims 13, 15 and 16. In response, Applicant respectfully submits that the problems with respect to claim 13 were obviated in the previously submitted Second Preliminary Amendment (copy enclosed). Problems regarding the dependency of claims 15 and 16 have been corrected herein.

The Examiner also rejects claims 13 and 14 based upon the allegation that the only means of expression of proteins or peptides is in a transformed host cell and that claims 13 and 14 therefore do not properly limit the scope of the claim from which they depend. In response, Applicant respectfully submits that there are also *in vitro* systems for producing proteins or peptides that would not necessitate transforming a host cell. Thus, claim 14 does, in fact, properly limit the scope of claim 12.

Although not used to reject claims, the Examiner points to two references, Mita, *et al.* (*Nucl. Acids Res.* 16:9351 (1988)); and Goldgaber, *et al.* (*Proc. Natl. Acad. Sci. USA* :7606-7610 (1989)). With respect to Goldgaber, the Examiner argues that the reference teaches the regulation of IL-1 mRNA by the APP promoter linked to a heterologous fusion protein. Applicant would like to point out two important features of this reference that they believe make it irrelevant with respect to the present claims. The first is that the reference is entirely concerned with transcription, *i.e.*, mRNA production, and does not recognize the presence of a region regulating translation (the mRNA-directed synthesis of protein) at all.¹ The second important feature of Goldgaber is that it never recognizes Applicant's 90 nucleotide translation enhancer as a distinct element that can be incorporated into a vector to regulate protein production. Although various DNA fragments upstream of the APP gene were ligated to a growth hormone gene to determine their effect on expression, none of the fragments include the full length translation enhancer element.

¹ Based upon the experiments summarized in Figure 2 of the reference, Goldgaber concludes that interleukin-1 increases APP gene transcription either by increasing the rate at which transcripts are made or decreasing the rate at which they are degraded (see page 7608, last paragraph).

The reference by Mita, *et al.* is concerned with sequence variations at the 5' end of the APP gene. Although a sequence corresponding to Applicant's translation enhancer is shown, it is, again, part of a longer sequence and not recognized as a distinct element that may be ligated to nonhomologous genes to increase the rate at which they are translated.

One of skill in the art reading either Goldgaber or Mita would receive no teachings that would allow them to carry out the assay now claimed. Neither reference suggests the presence of an element affecting translation or discloses Applicant's sequence as a distinct element. It is therefore respectfully submitted that these references do not render the claims presently pending as obvious.

Conclusion

In light of the amendments and discussion above, Applicant submits that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims presently pending in the application be allowed.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicant's undersigned attorney at (202) 419-7013.

Respectfully submitted,

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Date: November 17, 2003
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